UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION **This Document Relates to All Actions**	MDL No. 2875 Honorable Robert B. Kugler, District Court Judge Oral Argument Requested

DEFENDANTS' REPLY IN SUPPORT OF MOTION TO EXCLUDE THE OPINIONS OF LAURA PLUNKETT, PH.D.

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INTRODUCTION

Plaintiffs' opposition largely attempts to re-write or re-characterize Dr. Plunkett's opinions in an attempt to salvage them from being excluded. As set forth below, these efforts should be rejected.

First, plaintiffs cannot show that Dr. Plunkett's science-based opinions are admissible. Plaintiffs argue that Dr. Plunkett is qualified to offer risk assessment opinions, but such qualifications are irrelevant because Dr. Plunkett did not perform a risk assessment here. And plaintiffs' assertion that Dr. Plunkett has "personal knowledge" of chemistry ignores Dr. Plunkett's express testimony that she is not a chemist and is therefore unqualified to provide chemistry-based opinions.

Second, plaintiffs' arguments regarding the admissibility of Dr. Plunkett's legal and regulatory opinions also lack merit. Plaintiffs point to Dr. Plunkett's consulting experience as a basis for her regulatory opinions, but that experience has solely come as a paid litigation expert. Plaintiffs also ignore this Court's prior holding that legal opinions regarding bioequivalence, adulteration, and what the FDA "requires" impermissibly usurp the role of the Court and the jury.

Finally, Dr. Plunkett should not be allowed to testify about the regulatory conduct of Teva and Torrent (the "Finished Dose Manufacturers") because she did not undertake the type of review necessary to offer reliable opinions on that topic.

For these reasons, discussed further below, the Court should reject plaintiffs' arguments and exclude Dr. Plunkett's opinions from trial.

ARGUMENT

I. DR. PLUNKETT'S SCIENCE-BASED OPINIONS SHOULD BE EXCLUDED.

Dr. Plunkett's science-based opinions, including her opinions that valsartan drug products contained "NMDA and NDEA impurities" that rendered them "less safe" and that the presence of these alleged nitrosamine impurities resulted in "an increased cancer risk" (Plunkett Rep. at 4 (ECF 2285-3)) are inadmissible because: (1) she is not qualified to offer them; (2) she merely parrots other experts; and (3) "any exposure" opinions like hers have been widely rejected. Plaintiffs' attempts to defend these opinions are meritless and should be rejected.

A. Dr. Plunkett Is Not Qualified To Provide Science-Based Opinions.

As explained in defendants' opening brief, Dr. Plunkett is not qualified to provide certain science-based opinions, including opinions regarding "human health risks" and chemistry-based opinions. (Mem. at 5-8.) Plaintiffs do not seriously dispute either argument, attempting instead to re-characterize Dr. Plunkett's opinions in a different light to "fit" her purported qualifications. This argument should be rejected.

First, Dr. Plunkett is not qualified to testify about alleged "human health risks." Plaintiffs contend that Dr. Plunkett is only offering "risk assessment"

opinions, which she is qualified to offer as a toxicologist and pharmacologist. (Opp'n at 6-7.) But Dr. Plunkett did ***not*** perform an independent risk assessment analysis, as she ***repeatedly*** acknowledged at her deposition. (*See, e.g.*, Plunkett Dep. 14:22-15:6 (ECF 2285-4; ECF 2285-6) ("It's my understanding that there are other experts in this litigation that are either what I call risk assessors or specific causation experts that are doing those types of assessments."); *id.* 102:14-22 ("Q. Did you do all of the steps in a risk assessment methodology in this matter? . . . . A. I was not asked to do the full risk assessment for individuals , so I did not go to all the details of that. That was correct. I used the -- I used the methodology that I typically use when I'm developing regulatory opinions. And then in toxicology, I did a -- a hazard assessment[.]").) As such, even assuming Dr. Plunkett is qualified to opine on risk assessment, such qualifications are entirely irrelevant to her opinions here.[1]

In any event, even a cursory review of Dr. Plunkett's report and deposition belies plaintiffs' assertion that Dr. Plunkett's "science-based" opinions are limited

[1] For this reason, plaintiffs' cited cases in which courts found Dr. Plunkett qualified to offer a risk assessment opinion (Opp'n at 7) are inapposite. As one of those cases made clear, while Dr. Plunkett was qualified to opine on an "association" because she performed an "association analysis," she was prohibited from opining that the drug at issue "causes, carries an independent risk, or is a substantial contributing factor to permanent alopecia." *In re Taxotere Docetaxel Prods. Liab. Litig.*, MDL No. 16-2740, 2021 WL 3124494, at *3 (E.D. La. July 23, 2021) (cited in Opp'n at 7). Dr. Plunkett's opinions here should be equally limited to comport with her qualifications and the actual analysis – of lack thereof – that she performed in this case.

to "risk assessment" opinions based on her work as a toxicologist and pharmacologist. For example, Dr. Plunkett opines that "an increased cancer risk is associated with exposure to nanogram levels of NDMA." (Plunkett Rep. at 4; *id.* at 42 (Dr. Plunkett opining that "the nitrosamine impurities in valsartan drug products put patient health at risk. As a toxicologist and regulatory expert, the presence of impurities in drugs used chronically to treat health conditions that are probable human carcinogens (i.e., NDMA and NDEA) is a clear patient safety concern."); *see also* Plunkett Dep. 12:8-11 ("[Q. Y]ou testified that the presence of impurities in Valsartan increases the risk of cancer, right? A. Yes.").) This is clearly a medical opinion that Dr. Plunkett is indisputably unqualified to offer. Plaintiffs concede as much in their opposition, arguing that while "Dr. Plunkett provides several regulatory opinions that ***also touch on the risk posed by the nitrosamines in valsartan***," these opinions are nonetheless appropriate because "Dr. Plunkett had a reliable basis in concluding [that] 'the carcinogenicity of NDMA has been understood for many decades.'" (Opp'n at 8-9 (emphasis added) (citation omitted).) But, as courts have recognized, the reliability requirement of *Daubert* is not a substitute for an expert's complete lack of qualifications on a topic. *See, e.g., Alpha Pro Tech, Inc. v. VWR Int'l, LLC*, No. 12-1615, 2016 WL 5930868, at *3, *5 n.3 (E.D. Pa. Oct. 11, 2016) ("[T]he party offering the expert must demonstrate that the expert has the necessary expertise to provide reliable evidence."; "Because the

[c]ourt holds that [the proposed expert] lacks the qualifications to offer the proposed expert testimony, the [c]ourt need not move on to the second step of the analysis and evaluate the reliability of those opinions.") (citation omitted); *Diaz v. Johnson Matthey, Inc.*, 893 F. Supp. 358, 373, 377 (D.N.J. 1995) (noting that "[n]ormally, a ruling that a proffered expert is unqualified would end the inquiry" and finding that the expert's "testimony fails to meet either the qualifications or the reliability requirements of Fed. R. Evid. 702").

Second, Dr. Plunkett is not qualified to provide chemistry-based opinions because, in her words, "I'm not the chemist." (*See* Plunkett Dep. 176:23-177:12.) Plaintiffs argue that "Dr. Plunkett . . . has independent knowledge and basis for her 'chemistry related' opinions, including specifically related to the chemical structure of NDMA and NDEA." (Opp'n at 12.) This argument stops short of claiming that Dr. Plunkett is "qualified" to opine on chemistry – and for good reason. (*Id.*) Plaintiffs then cite to Dr. Plunkett's deposition testimony conceding that her purported chemistry "knowledge" amounts to a "more general . . . understanding and training based upon the toxicology training [she has] had." (Opp'n at 12 (quoting Plunkett Dep. 25:24-26:21).) Such purported "knowledge," however, is wholly insufficient to establish qualifications under *Daubert*. *See, e.g.*, *Castaic Lake Water Agency v. Whittaker Corp.*, No. 00-12613, 2002 WL 34700741, at *5 (C.D. Cal. Oct. 25, 2002) (finding an opinion unreliable because the expert sought to "offer the

opinion of a chemist as his own expert opinion in a field for which he is not qualified" given that "[c]hemistry is simply not [the expert's] field").

For all of these reasons, Dr. Plunkett is not qualified to offer her science-based opinions.

B. Dr. Plunkett's Chemistry-Based Opinions Are Inadmissible Because She Impermissibly Parrots Dr. Hecht.

Dr. Plunkett's chemistry-based opinions should also be excluded because they simply parrot opinions proffered by plaintiffs' expert Dr. Hecht. (*See* Mem. at 8-14.) Defendants detailed in their opening brief specific instances in which Dr. Plunkett wholly deferred to Dr. Hecht and chemists to substantiate her opinions that "Defendants could or should have had some knowledge about the risk of N-nitroso compound formation and the presence of the general class of nitrosamine impurities in valsartan"; and that ZHP conducted an "inadequate risk assessment." (*See, e.g.*, Plunkett Rep. at 15, 30; *see also* Plunkett Dep. 45:6-23, 177:20-178:8.)[2] Plaintiffs fail to address ***any*** of this evidence and testimony.

Plaintiffs contend that Dr. Plunkett's reliance on Dr. Hecht is proper because she "linked some of the opinions of Dr. Hecht to the applicable regulatory

[2] To the extent Dr. Plunkett offers any basis beyond mere parroting for her opinion that ZHP did not conduct an adequate risk assessment, Dr. Plunkett's opinion that ZHP's risk assessment was inadequate because it did not find nitrosamines is completely circular and therefore unreliable. (Mem. at 12-14.) Plaintiffs do not address or dispute this argument, and it is therefore conceded.

standards." (Opp'n at 11; *see also id.* at 12 ("Dr. Plunkett's 'chemistry-related opinions' interface with her regulatory opinions . . . .").) By way of example, plaintiffs assert that Dr. Plunkett opines that "it is the manufacturer's responsibility to ensure the quality of its valsartan" and "then notes that the introduction of NDMA and NDEA into valsartan was foreseeable ***as established by Dr. Hecht's expert report***." (*Id.* at 11-12 (emphasis added).) In other words, Dr. Plunkett attempts to pass off an opinion regarding foreseeability – i.e., whether ZHP "should have known" that impurities could form – based on Dr. Hecht's work. (*See* Mem. at 10-11 (citing Plunkett Dep. 81:17-21 ("It's beyond the scope of my work from the aspect of the chemistry of the reactions or the description of the foreseeability based upon an analysis of chemical process, which is what the chemist has done in this particular case."); *id.* 229:18-231:8 ("Dr. Hecht, the chemist, has many pages in his report where he discusses the -- these issues about the chemical reactions and the foreseeability.")).) This is parroting.

Plaintiffs also attempt to downplay Dr. Plunkett's reliance on Dr. Hecht by claiming that she "has an independent basis for her [chemistry] opinions." (Opp'n at 13.) But as explained above, this is not true, as conceded by Dr. Plunkett herself. And while plaintiffs try to minimize the issue by noting that Dr. Plunkett's report contains "limited citations to Dr. Hecht's opinions" (*id.*), they ignore entirely the ***30+ times*** she referenced Dr. Hecht and "chemists" at her deposition.

In sum, Dr. Plunkett's chemistry-based opinions are based primarily on an "unblinking reliance" on Dr. Hecht and must be excluded for this reason, too.

C. Dr. Plunkett's "Any Exposure" Opinion Is Contrary To Basic Toxicology Principles.

An expert's opinion that "any exposure" to a substance increases the risk of cancer is unreliable and should be excluded. (Mem. at 14-15.) Rather than dispute this unassailable legal principle, plaintiffs attempt to re-write Dr. Plunkett's opinion, claiming that she merely said "that prior to the recall there was no allowable amount of nitrosamines in valsartan." (Opp'n at 9, 11.) But Dr. Plunkett's opinion is not so limited, as she made abundantly clear at her deposition, including in a passage cited by plaintiffs in their opposition. (*See*, *e.g.*, *id.* at 9-10 (quoting Plunkett Dep. 15:7-16:22 ("[T]he presence of this ingredient in Valsartan, where there is no known safe dose generally of these impurities . . . generally the statement is that it increases the risk of cancer.")).) Indeed, Dr. Plunkett explicitly testified that an individual's "risk [of cancer] is increased with . . . exposure to the impurities in Valsartan" "because . . . there is no threshold or safe dose." (*See* Plunkett Dep. 113:25-114:10.) This is an improper "any exposure" opinion that should be excluded as unreliable.

Plaintiffs also attempt to re-write Dr. Plunkett's opinions by arguing that Dr. Plunkett merely "provides an opinion as to the specification for nitrosamines set by regulatory bodies and used in risk assessments to assess the safety profile of the

drug." (Opp'n at 9.)[3] But that is not what Dr. Plunkett says, and in any event, no regulatory body has said that "any exposure" to nitrosamines increases the risk of cancer, as explained above. Dr. Plunkett's opinion that "any exposure" to nitrosamines can contribute to cancer should therefore be excluded as unsupported.

II. DR. PLUNKETT'S LEGAL AND REGULATORY OPINIONS SHOULD BE EXCLUDED.

Defendants' opening brief explained that Dr. Plunkett's legal and regulatory opinions should be excluded from trial because: (1) she lacks the qualifications to offer them; (2) her regulatory opinions impermissibly parrot plaintiffs' expert Susan Bain (who is herself unqualified to opine on cGMP and regulatory matters); and (3) her opinions regarding the relevant regulatory requirements and defendants' compliance with the governing legal and regulatory frameworks would impermissibly usurp the role of the Court and the jury. (Mem. at 15-23.) Plaintiffs' arguments in response are meritless.

A. Dr. Plunkett Is Not Qualified To Provide Legal Or Regulatory Opinions.

Plaintiffs do not dispute that Dr. Plunkett is unqualified to offer legal opinions, and thus concede the issue. Although plaintiffs assert that Dr. Plunkett "has extensive regulatory training and experience through her decades of work as a

[3] Tellingly, plaintiffs provide no citation to this purported "opinion" from Dr. Plunkett's report or deposition.

regulatory consulting specialist to industry" (Opp'n at 14), this assertion glosses over the fact that Dr. Plunkett's consulting experience has predominantly come as a paid litigation expert. As one court noted in excluding Dr. Plunkett's opinions, "[h]er professional career has consisted predominantly of working as a paid consultant, including substantial service as a compensated expert. In the last five years she has testified approximately 65 times." *In re Mirena IUS Levonorgestrel-Related Prods. Liab. Litig. (No. II)*, 341 F. Supp. 3d 213, 254 (S.D.N.Y. 2018) (citation omitted).

While plaintiffs argue that some courts have admitted Dr. Plunkett's regulatory expert opinions, others have not, and defendants submit that those courts fulfilled their gatekeeper duties more properly. (*See* Mem. at 17-18 (citing Coordination Proceeding Special Title (Rule 1550(b)), No. 4247, 2006 WL 6122225 (Cal. Super. Ct. Aug. 1, 2006) (trial order)); *In re Tex. Second Region Baycol Litig.*, No. 0247408 et al., 2004 WL 5644643 (Tex. Dist. Ct. Jan. 26, 2004) (trial order); *see also* Tentative Ruling Permitting Dr. Plunkett's Ops. in Part ("*Echeverria* Ruling"), *Lloyd v. Johnson & Johnson (Pl. Eva Echeverria only)*, No. BC628228 (JCCP No. 4872) (Cal. Super. Ct.) (ECF 2285-3)).)

For all of these reasons, Dr. Plunkett is not qualified to provide the legal and regulatory opinions she seeks to offer in this case.

B. Dr. Plunkett's Regulatory Opinions Are Also Inadmissible To The Extent They Merely Parrot Dr. Bain.

As explained in defendants' opening brief, Dr. Plunkett's regulatory opinions are separately inadmissible to the extent they impermissibly parrot Dr. Bain. (Mem. at 19-20.) Plaintiffs respond that "Dr. Bain's name does not appear anywhere in Dr. Plunkett's expert report or reliance list, because Dr. Plunkett had not reviewed Dr. Bain's expert report prior to finalizing her own expert report." (Opp'n at 18.) But this statement conveniently ignores Dr. Plunkett's frequent invocations of Dr. Bain at her deposition, some of which plaintiffs highlight in their opposition. (*See id.* at 18-19 (citing Plunkett Dep. 145:3-147:19).) For example, defendants explained in their opening brief that while Dr. Plunkett seeks to opine that ZHP's "lack of conformity with applicable cGMPs and the presence of nitrosamines . . . rendered valsartan drug products adulterated as defined in FDA laws and regulations" (Plunkett Rep. at 5), Dr. Plunkett testified that she "wasn't doing a GMP compliance analysis, in the way other experts were doing" (Plunkett Dep. 185:23-25), and that "Dr. Bain is the one, and others, that are doing GMP compliance" (*id.* 148:16-17; *see also id.* 146:24-147:4). Plaintiffs fail to address this example.

C. Dr. Plunkett's Regulatory Opinions Are Inadmissible.

Finally, defendants argued that Dr. Plunkett's legal opinions regarding bioequivalence and, by extension, her opinion that ZHP's products were adulterated because they purportedly lacked bioequivalence (*see* Plunkett Rep. at 4-5), would

impermissibly usurp the role of the Court and the jury, as this Court has already held with respect to another plaintiffs' expert. (*See* Class Certification Ruling at 91 (ECF 2261) (excluding expert Dr. Najafi's opinions "about what is bioequivalence" because it "wades too far into the factfinder's domain"); *see also* Mem. at 20-22.) Plaintiffs fail to address this argument or this Court's prior ruling on the issue. Plaintiffs also fail to address any of the caselaw barring experts from offering opinions on a pharmaceutical company's compliance with applicable regulations.

Instead, plaintiffs contend that Dr. Plunkett should be permitted to opine that valsartan contaminated with NDMA and NDEA was adulterated because "the FDA *actually* deemed valsartan API with NDMA or NDEA present adulterated and valsartan finished dose with NDMA or NDEA present was recalled for that reason." (Opp'n at 16.) But once again, this argument mischaracterizes Dr. Plunkett's opinions. Dr. Plunkett's adulteration opinions are not limited to the FDA's express findings or the recalled products, but rather extend more broadly. In her words: "the lack of conformity with cGMPs and the presence of nitrosamines in valsartan API and finished drug products rendered valsartan drug products adulterated." (Plunkett Rep. at 42.) In any event, while it is proper for the FDA to decide whether or not ZHP complied with FDA regulations, it is ***not*** proper for Dr. Plunkett to make this determination; whether defendants met regulatory requirements is a factual issue, and it is black letter law that the jury decides all factual issues.

Plaintiffs also contend that Dr. Plunkett's "explanation of regulatory frameworks and decisions" is proper expert testimony. (Opp'n at 16.) But courts have previously excluded similar opinions by Dr. Plunkett. (*See* Mem. at 22 (citing *Newman ex rel. Newman v. McNeil Consumer Healthcare*, No. 10 C 1541, 2013 WL 9936293, at *5 (N.D. Ill. Mar. 29, 2013); *see also Echeverria* Ruling at 5).) Plaintiffs fail to address these decisions or to explain why a jury requires assistance to understand "regulatory frameworks and decisions." Jurors are more than capable of understanding regulations without subjecting them to Dr. Plunkett's subjective spin.

For these reasons, too, Dr. Plunkett's legal and regulatory opinions should be excluded at trial.

III. DR. PLUNKETT SHOULD NOT BE PERMITTED TO OFFER ANY OPINIONS REGARDING THE CONDUCT OF THE FINISHED DOSE MANUFACTURERS.

Plaintiffs' opposition confirms that Dr. Plunkett did not attempt to undertake the type of review necessary to offer reliable opinions as to the Finished Dose Manufacturers' (Teva and Torrent's) regulatory conduct. Plaintiffs argue that opinions such as those offered by Dr. Plunkett do not require review of voluminous company documents, mischaracterizing her testimony as simply stating a generic proposition that "it is still the finished dose manufacturers' responsibility to ensure that the API they are purchasing and the finished dose they are selling do not contain harmful impurities." (Opp'n at 19-20.) But as pointed out in defendants' motion,

Dr. Plunkett is not merely offering such generalized testimony; rather, she seeks to testify that the Finished Dose Manufacturers failed to meet those duties – and to do so without reviewing *any material to support her opinions.* (Mem. at 23-25.) Plaintiffs' opposition quotes her statement from her report that "Quality agreements do not absolve finished dose manufacturers from their responsibilities regarding drug quality" (Opp'n at 20 (citation omitted)), but Dr. Plunkett conceded at her deposition that she did not have criticisms of the Finished Dose Manufacturers' quality agreements with ZHP (Plunkett Dep. 316:21-317:13).

Plaintiffs also point to Dr. Plunkett's statement that "ANDA holders could have sold valsartan finished dose utilizing valsartan API quenched outside the presence of the drug product, resulting in the sale of valsartan finished dose without the presence of NDMA or NDEA impurities" (Opp'n at 20), but Dr. Plunkett did not review material specific to either of the Finished Dose Manufacturers in this case to evaluate when, how, or why they should have taken these steps. As she conceded at deposition, her opinion that Teva and Torrent should have identified the presence of NDMA is based solely on the fact that Novartis identified the presence of NDMA in 2018 (Plunkett Dep. 377:6-18, 381:9-14), although she does not know how Novartis came to structurally characterize NDMA in valsartan, despite claiming that Teva and Torrent should have done the same (*see id.* 377:19-380:24). Because Dr. Plunkett did not undertake *any* review to try and understand the conduct of the Finished Dose

Manufacturers in this case, her opinion is not based on a reliable methodology or on "good grounds."

Finally, plaintiffs' argument that Dr. Plunkett should be allowed to offer the opinion that the Finished Dose Manufacturers "should" have obtained access to the closed portion of the DMF should be rejected because it is merely the product of Dr. Plunkett's own say-so. Dr. Plunkett could not identify any source for the proposition that a finished dose manufacturer should obtain access to the closed portion of a DMF (Plunkett Dep. 365:3-367:2, 371:10-375:7), and she acknowledged that a finished dose manufacturer need not obtain access to the closed portion of the DMF to comply with cGMPs (*id.* 375:8-24). Accordingly, this opinion, too, is not grounded in any discernible methodology and should be excluded.

CONCLUSION

For the foregoing reasons, and for the reasons detailed in defendants' opening brief, defendants respectfully request that the Court exclude Dr. Plunkett's testimony from trial.

Dated: April 25, 2023

Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on April 25, 2023, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system, which will send a notice of electronic filing to all CM/ECF participants in this matter.

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